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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,849	10/29/2003	Jerome David	SPINE 3.0-414	7827

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EXAMINER

SWIGER III, JAMES L

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 10/695,849	Applicant(s) DAVID, JEROME	
	Examiner James L. Swiger	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 32-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 and 39-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/20/05; 6/28/04; 10/29/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 32-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/5/2006.

**it should be noted that the new claims added in the preliminary amendment filed on 3/29/2004 were omitted from the election restriction by the examiner, and this error was not caught by the representative for applicant either. However, they should have been included and have been examined as such. Therefore, claims 39-42 are included in the elected invention I. Invention I includes as follows: Claims 1-31, and 39-42.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

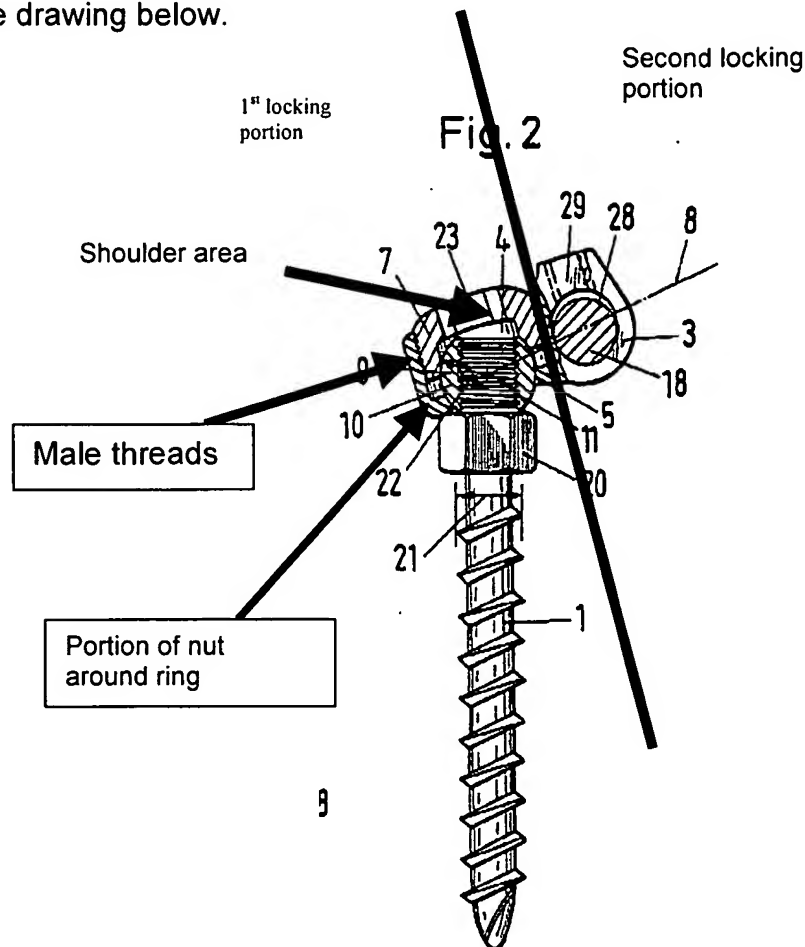
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-16, 19-31, and 39-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Studer et al. (US 6,146,383). Studer et al. discloses a bone fixation assembly comprising what is considered a unitary coupling element (see element in Fig. 2) that permits axial and sliding movement (9) of the coupling element (1) relative to the fixation element (Figs. 1 vs. 2), and that is also adapted to receive a spinal rod (18). The bone fixation assembly also has a first locking element to secure the head portion in the

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first bore and a second locking element adapted to secure the spinal rod in the second bore. See drawing below.



The coupling element also comprises a locking nut (7) in the first portion, and where the first locking element comprises a ball ring (9). The second bore via the spinal rod would therefore also have an axis that is transverse to the first bore, extending coplanar in the transverse direction. Further, once the second locking element (through bore 29, and would be considered as a set screw (24)) is set into the device, it is capable of being permanent if the user chooses it to be, and would be fully secure in the connection and stabilizing the spinal rod in place. The device further comprises male

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threads in the first bore (see drawing above) and wherein at least a portion of the locking nut surrounds the ball ring. The male threads would inherently fit into the female threads provided on the side of the first bore. The ball ring (9) is also in contact with the coupling member portion (5) at the bottom end of the ring, and the locking nut (7) at the top. The second locking assembly also comprises a set screw (24) that is capable of being seated in the locking member if the user wishes it to be. Also, the bottom portion of the ball ring (9) is tapered (see bottom portion of the first locking element in drawing above) to allow polyaxial motion. The fixation element also has a head portion (proximate to 22) that fits into the first locking element. Further, the ball ring and the locking nut associate with each other and with the head portion of the fixation element that is capable of exerting a radial force onto that element to secure the head of the screw in the coupling element. The set screw (24) or locking nut (7) may provide this means for providing radial forces.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Studer et al. '383 in view of Lange (US6,123,706). Studer et al. disclose the claimed invention except for a taper in the locking nut extending in opposite directions from that

The lines above represent the two tapers: one from the locking nut area (upper portion) and one from the bore (lower portion). These tapers provide a means for the spinal screws to be readily adjusted when they are in use. (See Col. 1, lines 35-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the bone fixation device of Studer et al. having at least opposing tapers in view of Lange to better allow the spinal fixation element to be adjusted in use.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Studer et al. '383 in view of Gu et al. (US 6,280,443). Studer et al. disclose the claimed invention except for a flared lip that cooperates with the coupling element. Gu et al discloses a taper (see drawing below) that allows for the set member bore (32) to better secure to the rod (Col. 4, lines 42-58).

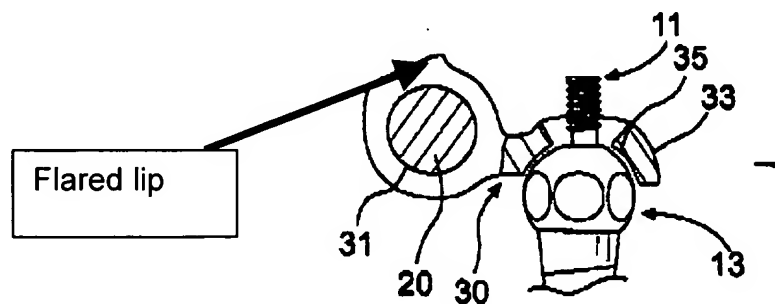


FIG. 4A

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the spinal fixation device of Studer et al. having at least a flared lip in view of Gu et al. to better secure the locking element and the rod in place and prevent the locking element from becoming removed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-


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5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLS

 6/27/06


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER